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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,372	07/11/2003	Mark G. Gilreath	P-4438-US	2855
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PEARL COHEN ZEDEK LATZER, LLP 1500 BROADWAY 12TH FLOOR NEW YORK, NY 10036			EXAMINER KISH, JAMES M	
			ART UNIT 3737	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/617,372

Applicant(s)

GILREATH ET AL.

Examiner

James Kish

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-11 and 18-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-11 and 18-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-4, 6-11 and 18-20 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2 and 4 recite the limitation "the functional element". There is insufficient antecedent basis for this limitation in the claim. It is believed that these are referring to the "functional unit" as described in the amended portion of Claim 1 and the Examiner has examined these claims based on this assumption.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-10 and 18-20 and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Ueda et al. (US Patent No. 5,681,260). Ueda discloses a guiding apparatus for guiding an insertable body within an inspected object. As illustrated in Figure 2, the insertable tip of the device comprises an imaging unit (see column 7, line 53 through column 8, line 12) and a functional unit is provided in several of the embodiments (see column 23, lines 33-34; it states, "... can be applied not only to an endoscope but also to a catheter."). As mentioned further in Claim 4, the functional element may encompass a catheter. As illustrated in Figure 1(a), a controlling apparatus is included in the Ueda device. In one embodiment, an LED is utilized as the illumination device powered by a battery (see column 18, lines 9-27 and Figure 27). Information and instruction is sent can be sent wirelessly between the device and the controlling apparatus (column 18, lines 27-38). Also, sensors such as pH and temperature sensors may be provided (column 18, lines 52-60). Within the process circuit, there is a memory unit, as described in column 24, lines 35-47).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 18-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Kucharczyk et al. (US Patent No. 6,626,902). Kucharczyk discloses a multi-lumen, multi-functional catheter system. As can be seen from Figure 1, the system comprises an in-vivo portion 2 and a non-inserted end connected to a computer 24 (also see column 12, lines 1-55). The computer interprets acquired measurements from the catheter and allows for an automation of the device column 9, lines 33-44; column 11, lines 27-30; column 13, lines 13-17). The device can be made out of soft, biocompatible plastics (column 20, lines 28-32). Possible tools that can be implemented with the catheter system can be found at column 8, lines 1-20. Claim 17 of Kucharczk includes the limitation of the central processor as well as dynamic and static memory, thereby allowing recording.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ueda et al. in view of Ishikawa et al. (US Patent No. 6,264,611). Ueda discloses a guiding apparatus for guiding an insertable body within an inspected object. As illustrated in Figure 2, the insertable tip of the device comprises an imaging unit (see column 7, line

53 through column 8, line 12) and a functional unit is provided in several of the embodiments (see column 23, lines 33-34; it states, "... can be applied not only to an endoscope but also to a catheter."). As mentioned further in Claim 4, the functional element may encompass a catheter. As illustrated in Figure 1(a), a controlling apparatus is included in the Ueda device. In one embodiment, an LED is utilized as the illumination device powered by a battery (see column 18, lines 9-27 and Figure 27). Information and instruction is sent can be sent wirelessly between the device and the controlling apparatus (column 18, lines 27-38). Also, sensors such as pH and temperature sensors may be provided (column 18, lines 52-60). Within the process circuit, there is a memory unit, as described in column 24, lines 35-47). However, the wireless transmission is not explicitly described as being RF energy. Ishikawa discloses a ball-shaped monitoring device for use with an instrument that is insertable into a human body. One application of the ball sensor is to place it at the tip of a guidewire used in interventional procedures, such as balloon angioplasty (column 4, lines 45-65). Figure 3 shows a balloon catheter system that could utilize the ball sensor. The figure shows a guidewire 10 at the non-inserted end. The device may be made of silicon or metals (column 15, lines 16-30). The ball sensor provides information to a remote processing system via RF signals. See Figure 7. Column 18, lines 15-38 discuss various applications of the ball sensor, including use with ultrasound and other imaging catheters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize RF energy as the means to provide a wireless connection as taught by Ishikawa as a well known method to those of skill in the art.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ueda et al. in view of Snoke et al. (US Patent No. 5,846,221). Ueda discloses a guiding apparatus for guiding an insertable body within an inspected object. As illustrated in Figure 2, the insertable tip of the device comprises an imaging unit (see column 7, line 53 through column 8, line 12) and a functional unit is provided in several of the embodiments (see column 23, lines 33-34; it states, "... can be applied not only to an endoscope but also to a catheter."). As mentioned further in Claim 4, the functional element may encompass a catheter. As illustrated in Figure 1(a), a controlling apparatus is included in the Ueda device. In one embodiment, an LED is utilized as the illumination device powered by a battery (see column 18, lines 9-27 and Figure 27). Information and instruction is sent can be sent wirelessly between the device and the controlling apparatus (column 18, lines 27-38). Also, sensors such as pH and temperature sensors may be provided (column 18, lines 52-60). Within the process circuit, there is a memory unit, as described in column 24, lines 35-47). However, Ueda does not state that the device is disposable. Snoke teaches a steerable catheter having a disposable module and sterilizable handle. The module includes an imaging means to be positioned within the body of the handle for transmitting images from within the human body (column 18, lines 55-63). It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate a disposable insert portion because these small or narrow working channels or lumens are difficult to clean and sterilize (column 2, lines 15-17).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Kish whose telephone number is 571-272-5554. The examiner can normally be reached on 8:30 - 5:00 ~ Mon. - Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JMK


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